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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[60Day-13-13KZ]
Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Ron Otten, at 1600 Clifton Road, MS D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Salt Sources Study - New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Stroke and coronary heart disease are the leading causes of morbidity and mortality in the United States, and account for billions of dollars in annual health care costs and productivity. Stroke and heart disease are directly related to high blood pressure, a condition that affects about 67 million Americans (31 percent of U.S. adults). Sodium intake directly and progressively increases blood pressure and subsequently increases the risk of heart disease and stroke. Recent evidence also indicates excess sodium can damage the heart, vessels, and kidneys without increasing blood pressure. It has been estimated that an average reduction of as little as 400 mg of sodium daily, or about 11% of average U.S. sodium intake, would prevent more than 28,000 deaths and save 7 billion health care dollars annually.

The Institute of Medicine (IOM, 2010) has recommended phased reductions in the sodium content of packaged foods and menu items, and voluntary actions by industry to reduce the sodium content of food. Public comments on these strategies have been solicited by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). In addition, the U.S. Department of Health and Human Services (HHS) has designated reduction in sodium intake as one of CDC's Winnable Battles, as a component of the Million Hearts™ initiative, and as a Healthy People 2020 objective.

There is a critical need for current, accurate information about the sources of sodium intake among diverse groups of adults living in the United States. A study conducted in 1991 (N=62) estimated that 77% of sodium consumed was from sodium added to packaged and restaurant foods during commercial processing, about 11% came from salt added at the table or during cooking, and 12% was naturally occurring (inherent) in food and beverages. Results from this study have been used to inform and prioritize efforts to reduce sodium in U.S. packaged and restaurant foods. For example, the data have been used to inform estimation equations for discretionary sodium intake (salt added at the table) and to estimate average total sodium intake. However, the study was not designed to produce estimates for population subgroups.

Since 1991, the U.S. has undergone demographic shifts in age, race, and ethnicity, changes in food consumption patterns, and changes in the geographic distribution of the population. CDC therefore plans to conduct a new Salt Sources Study to obtain updated information about the amount of sodium consumed from various sources (including sodium from processed and restaurant foods, sodium inherent in foods, and salt added at the table and during cooking) and to examine variability across population subgroups. Data collection will include an observational component as well as a sub-study designed to refine the accuracy of estimates of total sodium intake and discretionary sodium intake.

The Salt Sources Study will include participants in three distinct geographic regions: 1) Minneapolis/St. Paul, Minnesota, 2) Birmingham, Alabama, and 3) Palo Alto, California. Over a two-year period, a study center in each location will recruit 150 participants (total N=450) with the aim of selecting an equal number of adults ages 18-74 years by approximately 10-year age groups in each sex-race group, including whites, blacks, Hispanics, and Asians. A sub-study will be conducted among a subgroup of 150 of these participants (50 per site). One study center will serve as a study coordinating center and will transmit de-identified information to CDC through a secure web

site. CDC is authorized to conduct this information collection under section 301 of the Public Health Service Act (42 U.S.C. 241).

For the observational study component, CDC estimates that each study site will enroll 75 participants per year. After completing a screening process, each participant will complete a personal questionnaire, a tap water questionnaire, four 24-hour dietary recalls, and four qualitative food records. In addition, height and weight information on each participant will be collected, and each participant will provide samples of their cooking/table salt for independent analysis. Fifteen participants at each site will also provide water samples that will be analyzed to produce estimates of the amount of sodium in private sources of tap water.

The Salt Sources Study will include a sub-study to help determine the accuracy of estimates of total sodium intake and discretionary salt intake. We will ask participants to use a Study Salt for 11 days instead of their own household salt. The Study Salt contains a very small amount of lithium, a metal found in trace amounts in all plants and animals. Seventy-five respondents who are participating in the observational study (approximately 25 respondents from each study site) will provide additional information based on four 24-hour urine collections, four follow-up urine collection questionnaires, and three

follow-up questionnaires on Study Salt use.

Results from the Salt Sources Study will be used to inform public health strategies to reduce sodium intake, determine if substantial variability in sources of sodium intake exists by socio-demographic subgroups, and better inform estimates of salt added at the table used in Healthy People 2020 objectives related to sodium reduction.

Participation in the Salt Sources Study is voluntary. There are no costs to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
Adults aged 18-74 years	Telephone Recruitment and Screening	225	1	10/60	38
	Participant Questionnaire	225	1	10/60	38
	Discretionary Salt Use Questions from NHANES 2009	225	1	5/60	19
	Height and Weight	225	1	10/60	38
	Study Orientation and Scheduling	225	1	20/60	75
	Tap Water Questionnaire	225	1	5/60	19
	24-Hour	225	4	30/60	450

	Dietary Recall				
	Food Record	225	4	15/60	225
	Duplicate Salt Sample Collection	225	4	10/60	150
	Water Collection Form and Instructions	15	1	5/60	1
	24-hour Urine Collection	75	4	50/60	250
	Follow-up Urine Collection Questionnaire	75	4	10/60	50
	Study Salt Supplement Questionnaire	75	3	5/60	19
	Total				1,372

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